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Michihiro Ohnishi

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EXAMINER

FORMAN, BETTY J

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/550,302	<b>Applicant(s)</b> OHNISHI ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 13 April 2010 in which the previous rejections were traversed and new claims 14-20 were added. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 14 December 2009 under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) are maintained. It is noted that paragraph 4 of the previous Office Action incorrectly included Claims 8-13 in the rejection under 35 U.S.C. 102(b) over Quake. Claims 1, 3-4 and 7 were and remain rejected over Quake. Claims 8-13 were and remain rejected over Quake in view of Lough or Smith.

Applicant's arguments have been thoroughly reviewed and are discussed below. New grounds for rejection, necessitated by the added claims, are discussed.

Claims 1, 3-4 and 7-20 are under prosecution.

### ***Claim Objections***

2. Applicant is advised that should claims 14 and 15 be found allowable, claims 19 and 20 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New Claim 18 defines the gap part as having “a fixed sectional size”. Applicant points to ¶ 31-33, 44 and 46 for support of the newly added claims. The cited passages and the entire specification have been reviewed for support of the newly defined gap, however no support has been found. Therefore, the new claim appears to introduce subject matter that was not described in the originally filed specification.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 3-4, 7 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Quake et al (WO 02/40874, published 23 May 2002).

Regarding Claim 1, Quake teaches a first substrate (1122) and a second substrate (1130) connected to the first substrate defining connecting surface wherein the first and second substrates are grooved forming a channel (1126) and wherein the grooves have projections (1124 & 1128) wherein the gap is variable by moving the projections and wherein the gap is configured to block beads of a size greater than the gap (§ 21, § 208 and Fig. 11C).

Regarding Claim 3, Quake teaches the device wherein the first protrusion is opposed to the second protrusion (§ 208, lines 24-30).

Regarding Claim 4, Quake teaches the device wherein the gap is formed by inserting the protrusion of the first substrate into those of the second (i.e. interlocked, § 208).

Regarding Claim 7, Quake teaches the device wherein an inner wall of the channel is surface treated (§ 234).

Regarding Claim 16 and 17, Quake teaches the device wherein the substrates are made of glass or quartz (§ 129 & 240).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quake et al (WO 02/40874, published 23 May 2002) in view of Lough et al (U.S. Patent No. 5,900,481, issued 4 May 1999) or Smith et al (U.S. Patent No. 6,270,970, issued 7 August 2001).

Regarding Claims 8-13, Quake teaches a first substrate (1122) and a second substrate (1130) connected to the first substrate defining connecting surface wherein the first and second substrates are grooved forming a channel (1126) and wherein the grooves have projections (1124 & 1128) wherein the gap is variable by moving the projections and wherein the gap is configured to block beads of a size greater than the gap (§ 21, § 208 and Fig. 11C) but Quake is silent regarding the size, structure or composition of the beads.

However, silica particles of less than 10µm having hydroxyl functional groups were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lough et al.

Lough et al teach silica microbeads having a preferred size of less than 10µm (Column 3, lines 13-15, 25-26) and hydroxyl functional groups (Fig.2) wherein the surface is treated with a silane coupling agent (Fig. 2, Columns 3-4) whereby the nucleic acids for detecting are absorbed onto the surface of the beads (Abstract). Lough et al further teach the functionalization of the beads and surfaces provides differential immobilization chemistry between the bead-surface-nucleic acids (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the bead and surface functionality of Lough et al

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to the particles of Quake. One of ordinary skill in the art would have been motivated to do so based on the preferred differential immobilization of Lough (Abstract).

Furthermore, Smith teaches silica microbeads having a preferred size of less than 10 $\mu$ m (Column 12, lines 16-32) and immobilization-specific functional groups (Column 14, lines 45-56) wherein the surface is treated with a silane coupling agent (Column 14, line 57-Column 15, line 12) whereby the nucleic acids for detecting are selectively absorbed onto and released from the surface of the beads based on the presence and/or concentration of chaotropic salts (Column 16, line 58-Column 17, line 25) whereby the salts provide the nucleic acids in an unfolded state (Column 10, lines 43-57).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chaotropic salts of Smith et al to the hybridization methods of Quake. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing unfolded nucleic acids that are more thermodynamically stable than folded nucleic acids to thereby favor hybrid formation (Smith et al, Column 10, lines 43-57).

9. Claims 1, 3-4, 7 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002 and Quake et al (WO 02/40874, published 23 May 2002).

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Regarding Claim 1, Zenhausern teaches a microchip having a microchannel formed in a substrate using known techniques (§ 48), wherein the microchannel is provided with a gap wherein adjacent sides of the channel (grooved parts) have protruding parts (constrictions) forming the gap wherein the first or second protruding part is movable (i.e. “movable array of constrictions within the channel” § 61 and Fig. 2).

Zenhausern specifically teaches that the channeled structure “may be fabricated in a variety of ways” (§ 48) but does not specifically teach a channel formed between two grooved substrates. Zenhausern further teaches the channels are constricted but does not teach a size of the particle relative to the constriction (§ 47, 252).

However, channel formation between opposing grooved substrates having protrusions movable to block beads of a predetermined size was well known in the art at the time the invention was made as taught by Quake (§ 21 and 208). Quake further teaches that the protruding valves facilitate retention and analysis of analytes on the particles (§ 314).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the grooved substrates forming protruding valves of Quake to the device of Zenhausern. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the suggestion of Zenhausern to use any of a variety of known techniques to construct the channels. One of ordinary skill would have been further motivated to do so for the benefit of facilitating retention and analysis of analytes on the particles as taught by Quake (§ 314).



Regarding Claim 3, Zenhausern et al disclose the microchip wherein the gap is formed by opposed protruding parts (Fig. 2, ¶ 252).

Regarding Claim 4, Zenhausern et al disclose the microchip wherein the channel has protruding parts within the channels (Fig. 1 and 2) wherein the constriction inserts the protruding parts of the channels into the grooved channel of the opposing substrate, which are formed by bonding upper and lower substrate (¶ 48 and ¶ 60). Hence, the protrusion formed in one substrate is within the channel structure of the other substrate.

Regarding Claim 7, Zenhausern et al disclose the microchip wherein the inner surface of the microchannel is treated with biocompatible materials to prevent non-specific binding (¶ 49-50).

Regarding Claim 16 and 17, Zenhausern teaches the device wherein the substrate is glass or quartz (¶ 44) and Quake teaches the device wherein the substrates are made of glass or quartz (¶ 129 & 240).

Regarding Claim 18, Quake teaches the gap part (i.e. protrusion) is an "appropriate size and shape and spaced relative to one another" (¶ 208). The claim defines a "fixed sectional size".

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111). The claims are given the broadest reasonable interpretation consistent with the broad claim language and specification

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wherein neither sectional size nor fixed sectional size is defined. Given the broadest reasonable interpretation, the projections of Quake are encompassed by the claim because the projections have a defined size and spacing.

10. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002) and Quake et al (WO 02/40874, published 23 May 2002) as applied to Claim 1 above and further in view of Lough et al (U.S. Patent No. 5,900,481, issued 4 May 1999) or Smith et al (U.S. Patent No. 6,270,970, issued 7 August 2001).

Regarding Claims 8-13, Zenhausern et al disclose a microchip having a microchannel formed in a substrate using known techniques (§ 48), wherein the microchannel is provided with a gap having a sectional size variable by a movable protruding part i.e. movable array of constrictions (§ 61, 252).

Zenhausern et al further teach the channels are constricted to capture nucleic acid-immobilized on beads for analysis wherein the channel diameter is less than 10µm (§ 47, 252) but they do not specifically teach the bead diameter or hydroxyl functional groups for nucleic acid attachment. However, silica particles of less than 10µm having hydroxyl functional groups were well known and routinely practiced in the art at the time the claimed invention was made as taught by Lough et al.

Lough et al teach silica microbeads having a preferred size of less than 10µm (Column 3, lines 13-15, 25-26) and hydroxyl functional groups (Fig.2) wherein the surface is treated with a silane coupling agent (Fig. 2, Columns 3-4) whereby the

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nucleic acids for detecting are absorbed onto the surface of the beads (Abstract).

Lough et al further teach the functionalization of the beads and surfaces provides differential immobilization chemistry between the bead-surface-nucleic acids (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the bead and surface functionality of Lough et al to the particles of Zenhausern. One of ordinary skill in the art would have been motivated to do so based on the preferred differential immobilization of Lough (Abstract).

Smith also teach silica microbeads having a preferred size of less than 10 $\mu$ m (Column 12, lines 16-32) and immobilization-specific functional groups (Column 14, lines 45-56) wherein the surface is treated with a silane coupling agent (Column 14, line 57-Column 15, line12) whereby the nucleic acids for detecting are selectively absorbed onto and released from the surface of the beads based on the presence and/or concentration of chaotropic salts (Column 16, line 58-Column 17, line 25) whereby the salts provide the nucleic acids in an unfolded stated (Column 10, lines 43-57).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the chaotropic salts of Smith et al to the hybridization methods of Zenhausern and Lough. One of ordinary skill in the art would have been motivated to do so for the expected benefit of providing unfolded nucleic acids that are more thermodynamically stable than folded nucleic acids to thereby favor hybrid formation (Smith et al, Column 10, lines 43-57).

11. Claims 14-15 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zenhausern et al (U.S. Patent Application Publication No. 2004/0011650, filed 22 July 2002 and Quake et al (WO 02/40874, published 23 May 2002) as applied to Claim 1 above and further in view of Wilding (U.S. Patent No. 5,587,128, issued 24 December 1996) and/or Murphy (U.S. Patent No. 6,743,516, issued 1 June 2004).

Regarding Claims 14-15, 19-20, Zenhausern and Quake teach the elements of claim 1 as discussed above. New claims 14-15 and 19-20 define a surface treatment agent comprising trialkyl halogenosilane (e.g. triethylchlorosilane).

Zenhausern teaches a chlorosilane surface treatment agent (§ 196) and Quake teaches a chlorosilane surface treatment agent (§ 235) and Quake further teaches a hydrophobic coating (e.g. Teflon, § 234) but the references do not teach a trialkyl halogenosilane.

However, trialkyl halogenosilanes (e.g. trimethylchlorosilane (TMCS) and triethylchlorosilane (TECS)) were well known in the art at the time the invention was made as taught by Wilding and Murphy. Wilding teaches coating microfluidic channels with TMCS are useful for blocking biomolecule interaction with the substrate (Column 15, lines 30-40). Furthermore, Murphy teaches that TMCS and TECS provide highly durable hydrophobic coatings (Abstract, Fig. 4).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the trialkyl halogenosilane (e.g. TMCS or TECS)

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of Wilding and Murphy to the chlorosilane coatings of Zenhausern and Quake. One of ordinary skill in the art would have been motivated to do so based on their well-known use as taught by Wilding and Murphy. The artisan would have been further motivated to do so based on Quake's desired hydrophobic coating and further based on the fact that they provide a highly durable hydrophobic surface (Murphy, Abstract, Fig. 4).

### ***Response to Arguments***

12. Applicant argues that Quake does not teach a first and second substrate defining a microchannel in connecting surface wherein the connecting surface has a first groove part in the first substrate and a second groove part in the second substrate. Applicant points to ¶ 208 of Quake and asserts that the membrane (1122) is not a connecting surface between two substrates. Applicant acknowledges that the membrane has protrusions (1124) wherein a flow channel (1126) is formed at the connecting surface between membrane (1122) and lower section (1130), but asserts that the channel formed is not a microchannel in connecting surface between two substrates as claimed.

The argument has been considered but is not found persuasive. Applicant's argument appears to be based on an unclaimed interpretation of the instantly claimed substrate. However, neither the instant claims nor the specification provide a limiting definition of the substrate so as to define the substrate over the membrane of Quake. It is noted that newly added Claims 16 and 17 define the substrate as comprising and/or consisting essentially of glass or quartz. However, Quake teaches the membrane

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comprises the newly claimed substrate (¶ 240). It is maintained that Quake teaches the elements of the invention as detailed above.

Applicant further argues that Quake fails to teach the opposed protruding parts as required by Claim 3. As noted by Applicant, Quake teaches the protruding parts are formed on the membrane (1122) and opposing section (1130). The claim merely requires that the first protruding part is opposed to the second protruding part. Hence, protruding parts on opposed surfaces are encompassed by the claim. It is maintained that protruding parts of Quake formed on opposing structures are opposed (Fig. 11C).

Applicant traverses the rejection over Quake in view of Lough or Smith. Applicant asserts that the motivation suggested by the Examiner is conclusory and based on Applicant's teachings.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant reiterates that Quake does not teach the instantly claimed microchannel and further asserts that Lough and Smith do not cure the deficiencies of

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Quake. The argument is not persuasive for the reasons discussed above regarding Quake.

Applicant further argues that the motivation to combine provided by the Examiner is conclusory because the Examiner has not articulated "an adequate basis for why the skilled artisan considering Quake would look to Lough or Smith....". Applicant argues that Lough and Smith do not provide sufficient basis to modify Quake.

In response to applicant's argument that the teachings of Lough and/or Smith would not suggest modification of Quake, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). It is maintained that the teachings of Lough and Smith would suggest modifying the beads and assay of Quake based on the advantages discussed above.

On page 11 of the response, Applicant discusses the advantages provided by using trialkyl halogenosilane (e.g. triethylchlorosilane) as a surface treatment agent. Applicant points to ¶ 43-45 of the specification for related evidence.

The cited passages have been reviewed. However, it is noted that the specification only compares triethylchlorosilane to one other surface treatment i.e. dichlorodimethylsilane. The limited comparison is not sufficient to provide evidence of unexpected results or improvements. Furthermore, new claims 14 and 19 are not

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limited to triethylchlorosilane. Of the pending claims, only 15 and 20 are limited to triethylchlorosilane. Additionally, triethylchlorosilane was well known in the art to provide a highly durable coating as taught by Murphy and cited above. For all the above reasons, the newly defined surface treatment is obvious in view of the prior art.

Regarding the rejections over Zenhausern in view of Quake, Lough or Smith, Applicant argues that the Examiner offers no explanation for why the motivation/benefit of Quake is relevant to the deficiency of Zenhausern.

Zenhausern is merely silent regarding a specific process used to form the microchannel. Zenhausern does teach that the microchannels are made using well-known techniques (§ 45-48). Quake is cited for a teaching a well-know technique for forming a channel having projections. It is maintained that one of ordinary skill would look to Quake for construction of the channel based on Zenhausern suggestion to look to the prior art.

### ***Conclusion***

13. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman

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Primary Examiner  
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